

<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office	Docket No.: DERM1100-1	Serial No.: 09/375,609
	Applicants: Rheins and Morhean	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Filing Date: August 17, 1999	Group Art Unit: 1647

### U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE

### FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

<i>JS</i>	AP	Bunge, A. and Guy, R., "Improvement of Methodology for Assessing Bioequivalence of Topical Products," <a href="http://www.fda.gov/ohrms/dockets/ac/03/slides/3996S2 07 Bunge.pdf">http://www.fda.gov/ohrms/dockets/ac/03/slides/3996S2 07 Bunge.pdf</a> . <i>10/22/2003</i>
<i>JS</i>	AQ	"Draft Guidance for Industry on Topical Dermatological Drug Product NDA's and ANDA's-In Vivo Bioavailability, Bioequivalence, in Vitro Release and Associated Studies: Dermatopharmacokinetics (DPK) Method Issues", <a href="http://srpuh.phrma.org/letters/08.17.98.topical.derm.html">http://srpuh.phrma.org/letters/08.17.98.topical.derm.html</a> . PRMA 1998
<i>JS</i>	AR	"Washington Report: Skin Tape Stripping Method for Generic Dermatologic Drug Approval Remains in Question", <i>1999</i> <a href="http://www.aadassociation.org/old/washReports/dec99_washrep.html">http://www.aadassociation.org/old/washReports/dec99_washrep.html</a> . <del>(1996)</del> .

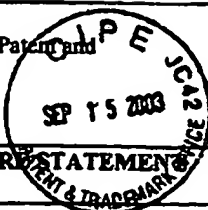
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	AF	Kondo et al., "Characterization of Epidermal Cytokine Profiles in Sensitization and Elicitation Phases of Allergic Contact Dermatitis as Well as Irritant Contact Dermatitis in Mouse Skin," <i>Lymphokine and Cytokine Research</i> , 13(6):367-375, Mary Ann Liebert, Inc. (1994). <i>Rev. of record, paper #7</i>
JS	AG	Rougier et al, "In Vivo Correlation Between Stratum Corneum Reservoir Function and Percutaneous Absorption," <i>J. Investigative Dermatology</i> , 81:275-278 (1983).
↓	AH	Rougier et al, "In Vivo Percutaneous Penetration of Some organic Compounds Related to Anatomic Site in Humans: Predictive Assessment by the Stripping Method," <i>J. Pharmaceutical Sciences</i> , 76:451-454 (1987).

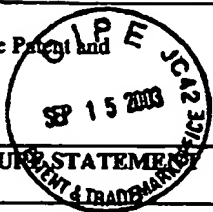
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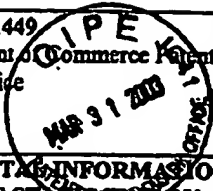
JS	AA	Brand et al., "IL-1 $\beta$ Protein in Human Skin Lymph Does Not Discriminate Allergic from Irritant Contact Dermatitis," <i>Contact Dermatitis</i> , 35:152-156, Munksgaard, Denmark (1996).
↓	AB	Graham, James H., "Basic Pathologic Changes in Skin," in "Dermal Pathology," Wd. J H Graham, W C Johnson, and E B Helwig, Harper-Row, Hagerstown, MD, pages 119-135 (1972)
	AC	Grängsjö et al., "Different Pathways in Irritant Contact Eczema? Early Differences in the Epidermal Elemental Content and Expression of Cytokines after Application of 2 Different Irritants," <i>Contact Dermatitis</i> , 35:355-360, Munksgaard, Denmark (1996).
	AD	Hoefakker et al., "In vivo Cytokine Profiles in Allergic and Irritant Contact Dermatitis," <i>Contact Dermatitis</i> , 33:258-266, Munksgaard, Denmark (1995).
	AE	Holleran et al, "Regulation of epidermal sphingolipid synthesis by permeability barrier function," <i>J. Lipid Research</i> , 32:1151-58 (1991).

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<b>SUPPLEMENTAL INFORMATION</b> <b>DISCLOSURE STATEMENT BY APPLICANT</b>	Filing Date: August 17, 1999	Group Art Unit: 1646

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<i>JS</i>		Torre and Gino, "Epidermal Cells on Stubs Used for Detection of GSR with SEM-EDX: Analysis of DNA Polymorphisms," <i>Journal of Forensic Sciences</i> , JFSCA, Vol. 41, No. 4, July 1996, pgs. 658-659, .
<i>/</i>		Garofano, L. et al., "PCR based analysis of epidermal cells found on adhesive tape," <i>Advances in Forensic Haemogenetic</i> , Vol. 6, 1996, pgs. 281-283. ( <i>Istituto di Anatomia e Fisiologia Umana, Universita degli Studi di Torino, Italy.</i> ) <i>Rev. of record, PTO 892 5/7/03</i>
<i>JS</i>		Garofano, L. et al., "Comparison of Powerplex® 16 System and Other Multiplex STR Typing Kits on Casework," ( <i>Reporto Carabinieri Investigazioni Scientifiche, Parma, Italia.</i> ), 2000
		Reference available at: <a href="http://www.promega.com/geneticidproc/ussymp11proc/default.htm">http://www.promega.com/geneticidproc/ussymp11proc/default.htm</a>

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